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09/729,653	12/04/2000	Biaoyang Lin	P-IS 4367	3087

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CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MINH-TAM DAVIS	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,27 and 30-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26* is/are rejected.

7)☒ Claim(s) *27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ [illegible] 2)☐

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 28-29, and adds new claims 30-32.

Since applicant has elected Group II, a PAMP polypeptide comprising SEQ ID NO:2, for action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the embodiments of claims 30-32 directed to a method for detecting prostate cancer have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03. Newly submitted claims 30-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

They are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as for making antibody.

Accordingly, claims 26-27 are being examined.

The following are the remaining rejections.

OBJECTION

Claim 27 appears to be free of prior art but is objected to as being dependent upon a rejected base claim 26, but would be allowable if rewritten in independent forms.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amino acid sequence shown as SEQ ID NO:2, **does not reasonably provide enablement for an amino acid sequence having one or more conservative substitutions relative to SEQ ID NO:2**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 26 is drawn to an amino acid sequence having one or more conservative substitutions relative to SEQ ID NO:2.

In the Declaration of 08/27/03, Applicant shows that using a mouse monoclonal antibody to a peptide encoded by nucleotides 2590-2968 of SEQ ID NO:1, which encodes SEQ ID NO:2, overexpression of a 151KDa PAMP polypeptide is found in prostate cancer tissue as compared to normal prostate tissue.

It is noted that an amino acid sequence having one or more conservative substitutions relative to SEQ ID NO:2 could have any amino acids within the full length of SEQ ID NO:2, including all of the amino acids of SEQ ID NO:2, substituted with any amino acids, provided they are conservative counterparts. Thus the claimed conservatively substituted variants of SEQ ID NO:2 could be chemically and structurally

completely different from SEQ ID NO:2, and would not necessarily be detected by said mouse monoclonal antibody.

The Declaration only discloses detection of overexpression of a single species, SEQ ID NO:2 in prostate cancer tissue, and this cannot be extrapolated to expression of a genus of conservatively substituted variants of SEQ ID NO:2 in prostate cancer tissue.

One cannot extrapolate the teaching in the specification and the Declaration of 08/27/03 to the scope of the claims, because although SEQ ID NO:2 seems to be overexpressed in prostate cancer tissue, it is unpredictable that its conservatively substituted variants are also overexpressed in prostate cancer tissue. It is well known in the art that variants of a sequence do not necessarily express at the same level as the corresponding wild type. The following teaching in the art, although drawn to polynucleotides would apply as well to polypeptides, because polynucleotides encode polypeptides. Schmid S et al, 2001, J comparative Neurology, 430(2): 160-71, teach that the variants flip/flop of the gene GluR are expressed at higher levels in neurons in the auditory braistem, as compared to the wild type GluR-A and GluR-B, and that neurons in the central nucleus of the inferior collicullus express high levels of GluR-B flip but only low levels of the other receptor subunits. Conner et al, 1996, Mol Brain Res, 42: 1-17, teach that full length trkB is found the hippocampus in patients with Alzheimer's disease, but not in hippocampi of either normal age-matched individual or patients with Huntington's disease, and that truncated trkB is found in senile plaques in hippocampus and temporal lobe in both patients with Alzheimer's disease and Huntington's disease, but not in normal brains of aged-matched individuals (page 8,

item 3.1.2). Thus in view of the teaching in the art one cannot predict that the conservatively substituted variants of SEQ ID NO:2 would overexpressed in prostate cancer tissue, and therefore, one would not know how to use the claimed conservatively substituted variants of SEQ ID NO:2.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

April 09, 2004